

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIVAGEN PHARMACEUTICALS, INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS, INC.,
AMNEAL PHARMACEUTICALS of
NEW YORK, LLC, AMNEAL
PHARMACEUTICALS LLC, AMNEAL
PHARMACEUTICALS PVT LTD., and
AMNEAL EU, LTD.,

Defendants.

C.A. No. 24-846-GBW

REDACTED - PUBLIC VERSION
Dated October 3, 2024

**LETTER TO THE HONORABLE GREGORY B. WILLIAMS FROM
ANNE SHEA GAZA REGARDING CROSS-MOTION FOR RECONSIDERATION OF
INJUNCTION ORDER AND RESPONSE TO NIVAGEN'S MOTION FOR
RECONSIDERATION OF THE BOND AMOUNT**

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Attorneys for Defendants

Dear Judge Williams:

Amneal writes in response to Nivagen's September 25, 2024 letter (D.I. 66) seeking reconsideration pursuant to D. Del. LR 7.1.5(a) of the bond amount order (D.I. 63) and cross-moves for reconsideration of the injunction order (D.I. 61) based on Nivagen's new evidence.

As this Court has recognized, "[a] motion for reconsideration is not an appropriate vehicle to reargue issues that the court has already considered and decided." *GE v. LPP Combustion, LLC*, No. 22-720-GBW, 2024 WL 3510307, at *1 (D. Del. Jul. 22, 2024) (citing *Justice v. Atty. Gen. of Del.*, 2019 WL 927351, at *2 (D. Del. Feb. 26, 2019); *Smith v. Meyers*, 2009 WL 5195928, at *1 (D. Del. Dec. 30, 2009) ("A motion for reconsideration is not properly grounded on a request that a court rethink a decision already made.")). It is not an opportunity to "accomplish repetition of arguments that were or should have been presented to the court previously." *Id.* (quoting *Karr v. Castle*, 768 F. Supp. 1087, 1093 (D. Del. 1991)). But that is exactly what Nivagen seeks here.

Nivagen's Reconsideration Request identifies no new evidence or error of law or fact that justifies reconsideration of the bond amount. To the contrary, Nivagen's bond letter (D.I. 59, "Nivagen Bond Letter") presents new evidence demonstrating the **lack** of irreparable harm in a brazen about face from its earlier submissions. To secure the injunction, Nivagen represented to the Court, with the support of a sworn declaration by Nivagen CEO Jay Shukla (D.I. 15), that an Amneal launch would decimate the market causing a parade of horrors and clear irreparable harm. But when arguing for a low bond amount in the Nivagen Bond Letter, Nivagen repeatedly argued that an Amneal launch would be insignificant and have almost no impact on the potassium phosphates market. (D.I. 59). In fact, Nivagen argued that Amneal would convert a **maximum of 1.5%** of the market [REDACTED]. (D.I. 59, at 2). Nivagen cannot have it both ways—total destruction when arguing for irreparable harm and near-zero impact when arguing for a low bond. Based on the current record, which the Court unfortunately did not have the benefit of and could not consider for its injunction order because Nivagen only presented it after entry of that Order, Nivagen cannot now credibly contend that it would be irreparably harmed. Since the Court did not have the benefit of Nivagen's new arguments and admissions when preparing and issuing the Memorandum Order and Opinion (D.I. 61, 62), Amneal respectfully requests that the Court reconsider its entry of the injunction in view of this critical new evidence. A finding of irreparable harm cannot be sustained based on the contents of the Nivagen Bond Letter and the injunction should be dissolved. D. Del. LR 7.1.5(a).

I. New Evidence of No Irreparable Harm Justifying Reconsideration of Injunction

The Nivagen Bond Letter contains critical new evidence—unavailable at the time the Court issued its injunction order—that goes directly to and proves lack of irreparable harm. (D.I. 59). As this Court has recognized, a motion for reconsideration is permitted to "correct manifest errors of law or fact or to present newly discovered evidence." *GE*, 2024 WL 3510307, at *1 (quoting *Max's Seafood Cafe v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999)). After repeatedly representing to the Court that it will be irreparably harmed if Amneal launches the only FDA-approved ready-to-use ("RTU") potassium phosphates product, Nivagen told the exact opposite story to try to convince the Court to enter a low bond amount. In doing so, Nivagen argued that Amneal will have almost no sales of the RTU product—even as an alleged "first mover"—due to an inability

to convert the multi-player potassium phosphates market. (D.I. 59). These assertions directly contradict Nivagen's prior evidence and arguments, upon which the Court relied to conclude that an earlier launch by Defendants would preclude Plaintiff from realizing first-mover benefits, cause reputational damage, and result in loss of employees, warranting reconsideration (and dissolution) of the injunction order. (D.I. 61, at 24).

Specifically, as shown in Exhibit A, in its PI briefing, through its CEO's declaration and that of Dr. Malaspina, Nivagen argued that it would be irreparably harmed because the benefits afforded to Amneal as a first-mover cannot be undone and asked the Court to grant the extraordinary relief of enjoining Amneal for the entirety of this Action. Now, in the Nivagen Bond Letter—after this Court already relied on Nivagen's PI briefing arguments—Nivagen boldly argues, *inter alia*:

- Amneal's market conversion rate would be "a maximum of 1.5%,"
- "Amneal is not known for having the best marketing and distribution channels for potassium phosphate injectable products,"
- Nivagen "expects Amneal's initial sales of its RTU product to be low," and
- "purchasers would view Amneal as an 'insignificant' player" because, unlike Nivagen, Amneal [REDACTED]

(D.I. 59, at 2; *see also* Exhibit A). Putting aside Nivagen's disparaging statements, if taken at face value, then how could Nivagen possibly be irreparably harmed if Amneal launches? Moreover, immediately after this Court enjoined Amneal for the entirety of this Action, Nivagen conceded that (1) it has [REDACTED] and (2) [REDACTED] the injunction may become unnecessary" because "damages after that point could very well be calculated." (D.I. 66, at 1). Amneal submits that these new admissions alone are sufficient for the Court to reconsider its finding of irreparable harm and dissolve the injunction order. (Ex. A).

II. The \$30,000,000 Bond Amount Is Intended to Protect Amneal And Nivagen Has Pointed to Nothing to Justify Reconsideration

If the Court is not inclined to dissolve the PI in view of Nivagen's about-face on irreparable harm, then Nivagen's request for reconsideration of the bond amount should be denied because it has neither pointed to nor alleged any error of law or fact or newly discovered evidence that can support reconsideration of the bond amount.¹ (D.I. 66). Rather, Nivagen's reconsideration request is rooted in its inability to secure financing for the bond.² Putting aside that Nivagen has provided

¹ Nivagen has neither pointed to any "manifest injustice," which "[g]enerally, [] means that the Court overlooked some dispositive factual or legal matter that was presented to it." *Rose v. Alt. Ins. Works, LLC*, No. 06-1818, 2007 WL 2533894, at *1 (D.N.J. Aug. 31, 2007) (collecting cases). Here, the Court did not overlook any evidence relating to the bond amount.

² The fact that Nivagen cannot secure a bond is unsurprising. Presumably, issuers consider the strength of the case and Nivagen's ability to cover the damages when deciding whether to issue a bond. Given the rampant speculation, and conspicuous absence of [REDACTED] [REDACTED]

no evidence of an inability to post the bond, Nivagen's after-the-fact argument entirely contradicts its representation that it made just two days earlier, *i.e.*, that Nivagen was "ready and able to post a bond." (D.I. 59, at 1 (stating that Nivagen "has already been in contact with several potential bond issuing organizations.")).³

Nivagen has no excuse for raising its new financing argument for the first time after the Court's bond order. Nivagen represented to the Court in a sworn declaration that [REDACTED] Nivagen also represented that it "expects" [REDACTED] It is unclear how Nivagen could now possibly be surprised by the bond amount ordered [REDACTED]

Moreover, in the Nivagen Bond Letter, it argued (D.I. 59, at 1) Amneal is in the best position to provide its projected profits for determination of a bond, and Amneal did exactly that analysis and supported it with expert testimony. (D.I. 57, 58). Unhappy with this result, Nivagen now tries to improperly manipulate the calculations using Amneal's lower numbers from its "ramp up" period. Even if it were appropriate to only provide a 6-month window—which it is not—a better proxy for the overall harm to Amneal, including Amneal's ability to be the "first mover," is to consider [REDACTED]. That same bond amount over six months would be about [REDACTED] (D.I. 66, at 2). Courts have rejected requests for piecemeal bonds and confirmed that a function of Rule 65 is to ensure a plaintiff has notice of the maximum amount of its potential liability without further litigation. *Nokia Corp. v. Interdigital, Inc.*, 645 F.3d 553, 557 (2d Cir. 2011); *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 804 (3d Cir. 1989) ("It is generally settled that, with rare exceptions, a defendant wrongfully enjoined has recourse only against the bond."). There is no basis for Nivagen to "revisit" or "reargue" the bond every six months to try to limit its exposure to damages.

In sum, Nivagen has not pointed to any new facts or law, court error, or any new evidence that could possibly support reconsideration of and/or lowering the bond amount. Nivagen asked this Court to enjoin Amneal for the entirety of this case, and that is the relief it received—the full

[REDACTED] there is no guarantee or even a reasonable likelihood that [REDACTED]
³ Nivagen's changed position is consistent with its actions throughout this proceeding of wanting to have its cake and eat it too: (1) on the one hand Amneal's first-mover advantage will cause immediate irreparable harm, on the other hand, Amneal will only obtain up to 1.5% market share; (2) on the one hand, [REDACTED] on the other hand, Nivagen cannot post a \$30,000,000 bond.

⁴ [REDACTED] It is unclear why Nivagen cannot obtain assistance from [REDACTED] who has been noticeably absent from these proceedings and may later be added as a party in this case.

amount is needed to protect Amneal from being wrongly enjoined.⁵ Now that an injunction issued, damage has begun to accrue. Amneal has canceled its [REDACTED] launch plans and has been harmed by being unable to deliver the only FDA-approved RTU potassium phosphates product to its customers and the industry. Amneal has already been forced to contact customers and pull marketing materials and advertisements. If Nivagen cannot secure the bond from the issuers [REDACTED], then the injunction should be immediately dissolved and Amneal should be able to proceed with launching its product.

Respectfully,

/s/ Anne Shea Gaza

Anne Shea Gaza (No. 4093)

Enclosure (Exhibit A)

cc: All Counsel of Record (via E-mail)

⁵ Nivagen's inability to financially post a bond for the amount of well-supported damages calculated by Amneal's expert supports that the bond is necessary to protect Amneal from the harm it has begun to incur.

Exhibit A

<u>Nivagen's New Evidence Warranting Reconsideration or Dissolution of the Preliminary Injunction</u>			
	Nivagen's Representations in the PI Briefing	The Court's Reliance on Nivagen's Representations in the PI Order	Nivagen's New Evidence Contradicting its Representations in the PI Briefing
Irreparable Harm Due to Loss of First-Mover Advantage	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	<ul style="list-style-type: none"> • “The Court is persuaded that Plaintiff would suffer immediate and irreversible harm <i>if it lost the right to be the first to practice its patented technology.</i>” D.I. 61 at 20 (citing Shukla Decl., ¶17, D.I. 32 at 6, and Malaspina Decl., ¶¶15-17). • “<i>If Defendants launch first, Defendants will immediately realize significant benefits at Plaintiff's expense by establishing long-lasting relationships</i> when early customers have no choice but to contract with the first-mover.” D.I. 61 at 22. 	<ul style="list-style-type: none"> • “Nivagen estimates that <i>Amneal could achieve a maximum of 1.5% rate of conversion</i> of the purchases from these contracted purchasers from the existing vial form potassium phosphate injectable products (from all manufacturers).” D.I. 59 at 2. • “This is because <i>Amneal is not known for having the best marketing and distribution channels</i> for potassium phosphate injectable products.” D.I. 59 at 2. • “<i>Nivagen would not expect each purchaser to place large orders</i> [from Amneal] until the reliability and user preference for this new product has been established.” D.I. 59 at 2. • “<i>The purchasers would view Amneal as an ‘insignificant’ player in the vial-form market</i> who does not have the endorsement from an established and highly visible market participant like [REDACTED]” D.I. 59 at 2.

			<ul style="list-style-type: none"> • Amneal's market conversion "<i>floor could be as low as 0.3%...</i>" D.I. 59 at 2-3.
Irreparable Harm Due To Loss of Reputation		<ul style="list-style-type: none"> • Plaintiff will suffer irreparable reputational harm, distinguishing <i>SmartSky</i> because "<i>the alleged infringer in SmartSky presented 'evidence demonstrating [the patentee's] ability to secure investments and customers subsequent to [the infringer's] announcement of its competing network.</i>" D.I. 61 at 23. • "In this action, <i>Defendants have presented no such evidence to counter Plaintiff's claims about the harm to its reputation absent an injunction.</i>" D.I. 61 at 23-24. 	<ul style="list-style-type: none"> • "Amneal has not revealed any partnership with a well-established vial-form market player such as [REDACTED] D.I. 59 at 2. • "The purchasers would view Amneal as an 'insignificant' player in the vial-form market who does not have the <i>endorsement from an established and highly visible market participant like [REDACTED]</i>." D.I. 59 at 2.
Nivagen's Irreparable Harm Requires a PI Through Trial		<ul style="list-style-type: none"> • "The bond amount shall remain in effect <i>during the pendency of this action</i> or until further Order of the Court." D.I. 63. 	<ul style="list-style-type: none"> • "Nivagen notes that it is possible that any preliminary injunction and its attendant bond will <i>not necessarily need to extend through a full trial on the merits.</i>" D.I. 59 at 4. • [REDACTED] "<i>the injunction could be dissolved</i>, with damages from that point on becoming an issue for trial." D.I. 59 at 4.